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10/802,058	03/17/2004	Anuj Chauhan	T2315-908542US02	1707

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MILES & STOCKBRIDGE PC
1751 PINNACLE DRIVE
SUITE 500
MCLEAN, VA 22102-3833

EXAMINER	
HAGOPIAN, CASEY SHEA	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
04/16/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/802,058	CHAUHAN ET AL.	
	Examiner	Art Unit	
	CASEY HAGOPIAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/17/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks, IDS and Terminal Disclaimer filed 12/17/2007.

Claims 1, 2, 6 and 7 are currently amended. Claims 16-19 are new. Thus, claims 1-19 are currently under examination.

Terminal Disclaimer

The terminal disclaimer filed on 12/17/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/454,836 has been reviewed and is accepted. The terminal disclaimer has been recorded. Accordingly, the provisional Double Patenting rejection has been withdrawn.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Action dated 8/16/2007:

Claim Rejections. 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-19 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "optically transparent" (see page 8 of Specification), does not reasonably provide enablement for a contact lens having

nanoparticles dispersed therein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification explains that the nanoparticle size and loading or directly dependent on the refractive index of the contact lens and the term, "optically transparent" is defined as the transparency equivalent to that of pHEMA or other material employed as a contact lens (page 8). It is suggested that applicant incorporate the limitations of claim 2 into claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 9, 12 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Resnick (US 2002/0141760 A1).

Resnick teaches a contact lens containing nanospheres that are incorporated directly therein (paragraphs 0003 and 0006). Resnick further teaches methods of incorporating drugs and therapeutic agents into the contact lens for the purpose of drug delivery to the eye (paragraph 0019 and claim 2) as well as a kit (title; fig. 3). Resnick refers to US patents 5,891,932 and 4,865,439 in paragraph 0006 for their teaching of

typical contact lenses that Resnick uses as starting materials. Said patents teach soft contact lenses and incorporation of 2-hydroxyethylmethacrylate as well as storing the lenses in saline solution.

Resnick is silent to the phrase "optically transparent", however the definition of said term in applicant's specification states, "a degree of transparency equivalent to that of p-HEMA or other material employed as a contact lens". The materials taught in Resnick read on said definition.

Thus, the teachings of Resnick render the instant claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 11, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Resnick (US 2002/0141760 A1).

Resnick teaches the elements discusses above.

Resnick is silent to the particulars of the kit claimed in the instant claims.

It is well within the knowledge of one of ordinary skill in the art to include a kit or article of manufacture because they provide a convenient mechanism to disperse products to consumers. Additionally, labels containing indications, directions, warnings, etc. are mandated. A practitioner would reasonably expect a kit comprising the drug delivery system of Resnick to provide a convenient mechanism to disperse the product to consumers as well as inform the consumer of indications, directions, and so on. Therefore, in Resnick it would have been obvious to one of ordinary skill in the art to package and label delivery system in a kit or article of manufacture.

It is also well within the knowledge of one of ordinary skill in the art to include a drug-saturated solution in the kit so the drug does not diffuse out of the contact lens are become diluted. A practitioner would reasonably expect the contact lens to have a therapeutically effective amount or concentration of drug. Therefore, in Resnick it would

have also been obvious to one of ordinary skill in the art to include a drug-saturated solution in a kit or article of manufacture.

Response to Arguments

It is appreciated that applicant's amendment to claim 2 more clearly defines the term "optically transparent", however according to the Office Action dated 8/16/2007 and the Interview Summary dated 11/28/2007, the examiner(s) suggested to incorporate the limitations of amended claim 2 into claim 1 in order to overcome the rejection under 35 USC § 112, 1st paragraph (i.e., scope of enablement). Applicant failed to do so and as such, said rejection is maintained for claims 1 and 4-15 and newly applied to new claims 16-19.

Applicant's amendment renders the rejections of the claims under 35 USC § 112, 2nd paragraph moot. Accordingly, all previous rejections under said statute have been withdrawn. It is noted however that new 112, 2nd paragraph rejections have emerged in light of applicant's amendment submitted on 12/17/2007.

Applicant's amendment renders the rejection of claim 12 under 35 USC § 101/112 moot. Accordingly, said rejection has been withdrawn.

Applicant's arguments with regards to the rejections of claims 1, 2, 4, 5, 9, 12 and 13 under 35 USC § 102 and claims 10, 11, 14 and 15 under 35 USC § 103 in view of Resnick have been fully considered but they are not persuasive.

Applicant argues that Resnick's invention has a very different focus and intent from that of the current invention and that Resnick does not provide enabling data for a person of ordinary skill to load nano/microspheres into contact lenses for the purpose of drug delivery (pages 8-9 of Remarks). Applicant further states that "Resnick presents enabling data to prepare contact lenses loaded with such particles so that the wearer of such lenses is protected from radiation" (page 9 of Remarks). In response, it is well established that a reference is presumed to have an enabling disclosure barring evidence to the contrary (see MPEP § 2121). As indicated in the Interview Summary dated 11/28/2007, it is the burden of applicant to submit evidence showing that the disclosure of Resnick is not enabling. Applicant's arguments are no more than allegations that find support neither in technical reasoning nor in evidence of record. For these reasons, applicant's argument is found unpersuasive.

Applicant argues that Resnick does not teach the release duration and does not provide enabling disclosure as to either extended delivery or time-release delivery as defined by claim 1 (page 9 of Remarks). In terms of enablement, the examiner's arguments submitted above hold true here as well. In addition, Resnick clearly teaches "drug delivery" and "time-release" at paragraph [0019] and claims 2 and 12. Thus, for these reasons applicant's argument is not persuasive.

Applicant argues that Resnick does not teach that the particles have to be designed specifically for a given drug such that they attenuate the drug release rates from the lens (page 10 of Remarks). In response, it is respectfully submitted that the instant claims do not include said limitations and as such, applicant appears to be arguing limitations into the claims. Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus, for this reason applicant's argument is found unpersuasive.

Applicant alleges that Resnick does not disclose "optically transparent" (page 10 of Remarks). In response, the examiner respectfully points out that applicant's argument is only pertinent to claims 2 and 3 because the term "optically transparent" is only recited in *those* claims. Also, applicant's specification at page 7 defines said term as "a degree of transparency equal to that of p-HEMA or other material employed as a contact lens". Resnick refers to US patent 5,891,932 and 4,865,439 at [0006] for their teachings of typical contact lenses that Resnick uses as starting materials. Said patents both teach contact lenses made from p-HEMA, thus in light of applicant's definition Resnick teaches the term "optically transparent". Furthermore, for a contact lens to function, it is inherent that a contact lens would be optically transparent. Applicant is reminded that once a reference teaching a product appearing to be substantially identical is made and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to show an unobvious difference (MPEP 2112). For these reasons, applicant's argument is found unpersuasive.

Applicant alleges that Resnick does not disclose an amount of nanoparticles from about 1 to about 5%, by weight, based on the weight of the contact lens, as defined by instant claim 3 (page 10 of Remarks). In response, it is respectfully submitted that claim 3 was not included in the rejection of record. Thus, applicant's argument does not bear any weight on the rejection at hand.

Applicant further alleges that Resnick does not provide instruction as to the main issue relevant to transparency including particle size, loading and refractive index contrast. In response, it is respectfully submitted that one skilled in the art would be knowledgeable of the different factors that affect transparency and that for a contact lens to function, it must be transparent. Thus, it is not necessary for Resnick to explicitly teach what a skilled artisan already knows. For these reasons, applicant's argument is unpersuasive.

Applicant alleges that Figures 1-3 in Resnick show systems that would yield a contact that would not be transparent and thus, teaches away from the present invention. In response, it is respectfully submitted that the Figures in Resnick do not represent the entire scope of the invention. The MPEP § 2123(II) states, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed…". Also, "[I]t is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue" (MPEP § 2125). Additionally, it is noted that applicant's argument is a conclusionary assertion for

which no supporting or scientific evidence is offered. Applicant is reminded that "arguments of counsel cannot take the place of factually supported objective evidence" (MPEP § 2144.08(II)(B)). For these reasons, applicant's argument is unpersuasive.

Applicant alleges that Resnick does not provide an enabling disclosure related to extended delivery or time-release delivery of lidocaine, timolol, ciproflaxin, cyclosporine A, pilocarpine, anti-protozoal drugs, steroids, non-steroids or antibiotics as defined by claim 6 (page 10 of Remarks). As discussed previously, it is well established that a reference is presumed to have an enabling disclosure barring evidence to the contrary (see MPEP § 2121). As indicated in the Interview Summary dated 11/28/2007, it is the burden of applicant to submit evidence showing that the disclosure of Resnick is not enabling. Applicant's arguments are no more than allegations that find support neither in technical reasoning nor in evidence of record. Additionally, it is respectfully pointed out that claim 6 was not included in the rejection of record. Resnick generically teaches "drug delivery" and "time-release" at paragraph [0019] and claims 2 and 12. Thus, applicant's argument does not bear any weight on the rejection at hand.

Applicant alleges that Resnick does not provide an enabling disclosure related to nanoencapsulating an ophthalmic drug with an encapsulation material in an oil-in-water emulsion as defined by claim 7. In response, it is respectfully pointed out that claim 7 was not included in the rejection of record. Additionally, said claim is deemed a product-by-process claim and as such determination of patentability is based on the product itself, not by the method in which it is made. Applicant is reminded that if the product in the product-by-process claim is the same as or obvious from a product of the

prior art, the claim is unpatentable even though the prior product was made by a different process (MPEP 2113). Thus, applicant's argument does not bear any weight on the rejection at hand.

Applicant alleges that Resnick does not provide disclosure related to encapsulation materials as defined by claim 8. In response, it is respectfully pointed out that claim 8 was not included in the rejection of record. Thus, applicant's argument does not bear any weight on the rejection at hand.

For these reasons, applicant's arguments are unpersuasive. Therefore, the rejection under 35 USC § 102 over Resnick is maintained.

NEW REJECTIONS

The following rejections are new in light of applicant's amendments submitted 12/17/2007:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 includes the limitation "wherein said diffusion provides extended or time-release delivery of said ophthalmic drug". Said limitation is indefinite because diffusion

doesn't provide release characteristics; the materials utilized do. Claims 2-19 all depend ultimately from claim 1.

Claim 6 includes the limitation "wherein said ophthalmic drug is lidocaine, timolol, ciproflaxin, cyclosporine A, or pilocarpine or wherein said drug is an antiparisitic, an anti-protozoal, a steroid, a non-steroid, an antibiotic or mixtures thereof". It is unclear what the meets and bounds of claim are because the claim includes a Markush group of particular drugs as well as drug classes. Also, "a non-steroid" reads on any drug that does not fall into the steroid category. Did applicant intend the limitation to be a non-steroidal anti-inflammatory, or NSAID?

Claim 8 depends from claim 7. Claim 8 includes encapsulation materials used to nanoencapsulate a drug. Said encapsulation materials recited do not all appear to be required to be in nanoparticle form. For instance, PLGA particles and gelatin are recited. The specification at pages 9 and 10 list the same materials as described in the claim, however for the purposes of consistency, antecedent basis and properly further limiting a claim, it is suggested that all of the encapsulation materials are accompanied by language, such as "nanoparticles", that properly describes that said materials are in nanoparticle form.

Claim 18 includes the limitations "said non-steroid". Similarly to claim 6, it is unclear if applicant intended to refer to any non-steroid drug or a non-steroidal anti-inflammatory.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Resnick (US 2002/0141760 A1) in view of Darougar et al. (USPN 6,264,971 B1).

Resnick teaches the elements discussed in the above paragraphs under the section heading *Maintained Rejections*.

Resnick is silent to the particular ophthalmic drugs recited in claims 6 and 17-19.

Darougar teaches an ocular insert that release an ophthalmic drug in a controlled, sustained fashion (abstract). Said ophthalmic drugs include antibiotics such as gentamycin, anti-microbial drugs, anti-inflammatories such as prednisolone acetate, non-steroidal agents such as diclofenac (i.e., Voltaren), pilocarpine and timolol (col. 5, line 41 – col. 6, line 16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include said particular ophthalmic drugs in nanoparticles in the contact of Resnick with a reasonable expectation of success because the prior art suggests that a) said drugs are well-known for the purpose of treating the eye as well as b) the contact of Resnick containing said drugs would facilitate improved controlled drug delivery to the surface of the eye.

Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Resnick (US 2002/0141760 A1) in view of Raut (US 2003/0216431 A1).

Resnick teaches the elements discussed in the above paragraphs under the section heading *Maintained Rejections*.

Resnick is silent to the particular ophthalmic drugs recited in claims 6 and 16.

Raut teaches ophthalmic pharmaceutical compositions for topical administration to the eye (abstract). In a particular embodiment, Raut includes pyrimethamine (paragraph [0117]). It would have been obvious to one of ordinary skill in the art at the

time the invention was made to include pyrimethamine in nanoparticles in the contact of Resnick with a reasonable expectation of success because the prior art suggests that a) pyrimethamine is well-known for the purpose of treating the eye as well as b) the contact of Resnick containing pyrimethamine would facilitate improved controlled drug delivery to the surface of the eye.

Conclusion

All claims have been rejected; no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey Hagopian/

Examiner, Art Unit 1615

/Carlos A. Azpuru/

Primary Examiner, Art Unit 1615